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June 7, 2005

VIA FACSIMILE & REGULAR MAIL

Commissioner Robert E. Nicolay
Chairman, Certificate of Need Task Force
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland 21215

**RE: MARYLAND AMBULATORY SURGICAL ASSOCIATION COMMENTS
ON CERTIFICATE OF NEED PROGRAM IN MARYLAND**

Dear Chairman Nicolay:

On behalf of the *Maryland Ambulatory Surgical Association (MASA)*, an organization representing single and multi-specialty practices across the state of Maryland, please accept these written comments regarding the Certificate of Need (CON) program in Maryland. Over the past several years, MASA has provided the Maryland Health Care Commission (MHCC) with the industry's position, comments and concerns on the CON process and program.¹ In addition, MASA has met with commission staff on numerous occasions to discuss issues impacting ambulatory surgery, including certificate of need.

These comments to the Task Force on the Certificate of Need program in Maryland are organized in four brief sections: (1) an overview and philosophy of the ambulatory surgical centers industry in Maryland; (2) MASA's general position on certificate of need; (3) MASA's response and thoughts on the three areas outlined in the Meeting Announcement dated May 12, 2005; and (4) MASA's conclusions. In addition, we would like to offer our industry's expertise to the Commission and the Task Force as it works on this and other very important issues surrounding the CON program in Maryland that directly and indirectly impact the freestanding ambulatory surgical facility industry.

¹ Most recently MASA commented on the document entitled "*An Analysis and Evaluation of Certificate of Need Regulations in Maryland - Working Paper: Ambulatory Surgical Facilities and Services*", dated September 19, 2001.

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**OVERVIEW AND PHILOSOPHY OF AMBULATORY SURGICAL CENTERS
NATIONALLY AND IN MARYLAND**

Nationally

Ambulatory surgery centers (ASCs) are facilities where surgeries that do not require hospital admission are performed. They provide a safe, cost-effective and convenient environment that is less stressful than what many hospitals offer. ASCs may perform surgeries in a variety of specialties or dedicate their services to one specialty, such as eye care. Each year, over eight million surgeries are performed in more than 4,000 ASCs across the United States. Procedures performed in these centers include ophthalmology, gastroenterology, orthopedic, ENT (ear, nose & throat), gynecology, and plastic surgery. Patient satisfaction is a hallmark of the ASC industry. The U.S. Department of Health and Human Services Office of the Inspector General surveyed Medicare beneficiaries who had one of four procedures in an ASC. He found that 98% of the people were satisfied with their experience.

One reason for high patient satisfaction is convenient scheduling. According to the Federated Ambulatory Surgical Association (FASA) Outcomes Monitoring Project, 75% of ASCs started more than 95% of their cases on time. Another reason patients like ASCs is value. Studies have shown that on average, procedures performed in ASCs cost 47% less than the same procedures at hospitals. Furthermore, every study ever done has shown that the quality of care delivered at ASCs is equal to or better than comparable hospital care.

ASCs are some of the most highly regulated health care providers in the country. Medicare has certified 85% of the centers, and 43 states require ASCs to be licensed. These states also specify the criteria that ASCs must meet for licensure. Both states and Medicare survey ASCs regularly to verify that the established standards are being met. In addition to state and federal inspections, many surgery centers choose to go through voluntary accreditation processes conducted by their peers. ASCs that want to demonstrate a commitment to quality can seek accreditation from one of four accrediting bodies (AAAHC, JCAHO, AAAASF, and AOA). All four organizations are recognized by Medicare for their rigorous adherence to the highest standards of quality care. All accredited ASCs must meet specific standards that are evaluated during on-site inspections. As a result, patients visiting accredited ASCs can be assured that the centers provide the highest quality care.

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Maryland

In Maryland, ambulatory surgical centers are required to follow the CON statutes (Health General Article §§19-114 through 19-131) as well as the statutory oversight provisions under Health General Article §§19-3B-01 et seq. The origins and philosophy of ASC's in Maryland were to provide quality assurance and quality health care to patients seeking needed ambulatory services. These services were provided under conditions that were safe, excellent in quality, and cost effective for the patient, provider and payers. In 2003, over 433,000 cases were performed at freestanding ambulatory surgical facilities in Maryland.² Most important, ASC's offered safe and effective ambulatory surgical services in a setting that was comfortable for the patient and where the patient could receive the best attention and care. Delivering these services requires specialized skills of very qualified surgical specialists and support staff including anesthesiologists, certified registered nurse anesthetists, operating room technicians, nurse practitioners, nurses and administrative personnel who have advanced training and are concerned about one thing – the patient's well being, safety and health. This is the philosophy that MASA has supported since it was formed in the early 1990's.

MASA'S GENERAL POSITION ON CERTIFICATE OF NEED

As we indicated in 2001, MASA is in full support of a more free market economy with access to and equal competition within Maryland's health care system. The ambulatory surgical industry in Maryland was founded on the premise that more competition will bring about reduced costs and greater quality of care to the patient. Encompassed in this philosophy is the support of a health care system that looks to reduce health care costs to the consumer, promote and protect patient safety, as well as provide quality assurance and quality health care to patients seeking needed health care services. Although MASA fully supports a free market system; it understands the need for and appropriates the role that regulatory oversight by the state plays in protecting patient safety and quality of care.

MASA fully supports the continuation of a regulatory system that works to promote both the industry and consumer safety and protection. **It is the position of the Maryland Ambulatory Surgical Association that this regulatory system continues a CON policy that provides the MHCC with appropriate tools and oversight of the ambulatory surgical industry.**

² Maryland Ambulatory Surgery Provider Directory, September 2004, Maryland Health Care Commission, Statistical Profile of Ambulatory Surgery Centers: Maryland, 2003, page 3.

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MASA'S RESPONSE AND THOUGHTS ON THE THREE AREAS OUTLINED IN THE MEETING ANNOUNCEMENT DATED MAY 12, 2005

Scope of Services and Facilities

In order to comment on the scope of services and facilities as they relate to the CON process, it is important to review the recommendations made in 2001-2002 concerning the Commission's CON policy related to ASCs.³ Consistent with MASA's position, we are supportive of the MHCC report's first recommendation that the Commission make no changes in ambulatory surgical facilities CON policy.⁴ In the words of one surgery center, "if it's not broke, don't fix it." Continuity in policy for the regulated industry of ambulatory surgery makes it desirable that the current policy on certificate of need for ASC's remains unchanged and in doing so, would eliminate the potential for any unanticipated consequences of policy change. MASA does not favor expanding CON regulation or making slight modifications which may have unintended consequences. Eliminating the CON process is not a position that is supported by MASA. In addition, it is an option in which patient safety, quality assurance and consumer protections may be adversely impacted and effected.

MASA continues to be fully supportive of developing a consensus among MHCC, the Office of Health Care Quality (OHCQ) and the industry on definitions of "operating room" and "procedure room" to be employed in both CON regulation and licensure.⁵ There is no definition of "procedure room" currently in the CON regulations. Current regulations lack specificity with respect to both "operating room" and "procedure room". What can they be used for? What types of procedures? What types of equipment can be used in each? MASA is concerned that without more specific guidelines in this specific area, quality of care could be at risk and an uneven playing field could be created in the ambulatory surgical industry.

Enhancement of Application Review Process

MASA has no comments at this point in time on the enhancement of the application review process.

³ Analysis and Evaluation of Certificate of Need Regulation in Maryland: Phase II - Final Report to the Maryland General Assembly, January 1, 2002, Executive Summary, pp. ii-iv.

⁴ Recommendation 4.0 on page ii of the Executive Summary

⁵ Recommendation 4.3 on page iii of the Executive Summary

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Enhancement of Monitoring of CON projects

MASA has no comments at this point in time on the enhancement of the monitoring of CON projects.

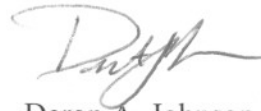
MASA'S CONCLUSION

We appreciate this opportunity to comment before the Task Force on behalf of the Maryland Ambulatory Surgical Association. As we have outlined above and in our oral comments, MASA believes Maryland's current CON policy should remain in effect, without changes at this point in time, for ambulatory surgery. MASA is strongly opposed to eliminating the CON requirement for ambulatory surgical facilities and services. MASA believes that the system in place protects patient safety and provides appropriate oversight of the industry by the state. Finally, MASA believes that in order to better clarify the CON rules and regulations, tighter definitions of "operating room" and "procedure room" are needed in regulation. MASA looks forward to working with MHCC staff and the members of the task force as the Task Force reviews the CON program and works to fulfill its goal to enhance the credibility and integrity of the CON program and make recommendations to enhance and improve the program.

Sincerely,



J. William Pitcher
MASA Legislative Counsel



Deron A. Johnson
MASA Legislative Consultant